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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,873	10/30/2006	Brian P. Janowski	79982	5898

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FITCH EVEN TABIN & FLANNERY
120 SOUTH LASALLE STREET
SUITE 1600
CHICAGO, IL 60603-3406

EXAMINER	
FISHER, ELANA BETH	
ART UNIT	PAPER NUMBER
3733	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,873	JANOWSKI ET AL.	
	Examiner	Art Unit	
	ELANA B. FISHER	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7,12,13,16,20,21,24-26 and 29-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7,12,13,16,20,21,24-26 and 29-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/10/2008; 01/10/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 16 recites the limitation "the insert lower surface" in the second line of the claim. There is insufficient antecedent basis for this limitation in the claim.

3. Claim 16 recites the limitation "staked portions of the anchor member head" in the fourth line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 7, 12, 21 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Yuan et al. (U.S. Patent 6,565,565).

Yuan et al. disclose a spinal fixation system (FIG 12A) comprising: a bone anchor member (224) for being secured to a vertebral bone of the spine and having an enlarged head (225) at one end thereof. Further, there is an elongate member (212) for extending generally along the spine, and a coupling device (222) for securing the elongate member relative to the bone anchor member. A seat (229) of the coupling device has a bore about

which the seat extends and sized to allow the anchor member to extend through the bore in a plurality of orientations with the head engaged against the seat (FIG 13). Additionally, there is a cam lock member (220) of the coupling device having a cam surface (287) which cooperates to push the elongate member downward with the cam lock member being fixed against translation during turning thereof for clamping the head of the anchor member against the seat to fix the anchor member in one of the orientations thereof with the elongate member secured between the cam lock member and the anchor member head (FIG 13).

The elongate member (212) is a spinal rod having a convexly curved surface, the cam surface (287) of the cam lock member is a bottom surface thereof that includes a concave surface portion and ramp surface portions on either side of the concave surface portion (FIG 12B). A saddle member (220b) of the coupling device including an upper cam surface (298) and a lower concave surface (299) with the upper cam surface configured to cooperate with the cam surface portions of the cam member for driving the lower concave surface into tight fitting engagement on the rod surface (FIG 13). The coupling device (222) includes walls (230, 232) extending upward from the seat by a predetermined distance with the camming between the cam lock member and saddle member allowing the predetermined distance to be minimized for providing a low profile for the coupling device (FIG 13). Additionally, the bone anchor member (224) is integral with the coupling device (222; FIG 13).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 30, 33, and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yuan et al. (U.S. Patent 6,565,565).

Yuan et al. disclose a spinal fixation system (FIG 12A) for fixing an elongate member in a desired position relative to a patient's spine, the spinal fixation system comprising: a bone anchor member (224) for being secured to a vertebral bone of the spine, a coupling member (222) having an axis (y) and an internal space (227) for receiving the spinal rod extending therethrough in a direction transverse to the coupling member axis (FIG 12A), and a cap member (220a) for being turned about the coupling member axis to a locked position thereof and locking the elongate member in the coupling member. Additionally, there is a saddle member (220b) disposed between the cap member and the elongate member for being tightly engaged against the elongate member with the cap member in the locked position (FIG 13), and a connector member (298) for keeping the cap member and saddle member assembled together and allowing the saddle member to shift axially along the coupling member axis upon turning of the cap member (FIG 13).

Further, there are cam surfaces (287) between the cap member and the saddle member configured so that turning of the cap member toward the locked position causes

the saddle member to be driven axially toward the elongate member without requiring axial movement of the cap member (FIG 13). The connector member (298) includes an axially intermediate cam portion that frictionally holds the cap member and the saddle member closely adjacent to each other and allows the saddle member to shift axially relative to the cap member as the cap member is turned. The cam surfaces comprise a bottom surface(287) on the cap member and an upper surface on the saddle member (FIG 12B), such that the upper surface of the saddle member has an elongate configuration extending within the internal space of the coupling member (FIG 13). Additionally, and the coupling member (222) and the cap member (220a) have detents therebetween to provide a tactile indication of different rotary positions of the cap member during turning thereof (FIG 12A).

However, Yuan et al. fail to disclose that the connector member (298) is distinct from the cap member (220a) and the saddle member (220b). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the coupling member be distinct from the cap and saddle members, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

8. Claims 31-32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yuan et al. (U.S. Patent 6,565,565) as applied to claim 30 above, and further in view of De Coninck et al. (WIPO Publication 2003/024343).

Yuan et al. disclose a spinal fixation system according to claim 30 above, and additionally disclose that the cap member (220a) includes a central opening (288) that

receives the connector member (298). However, Yuan et al. fail to disclose that the connector member (298) comprises a spring clip. De Coninck et al. disclose a spinal fixation system comprising a cap member (4), a saddle member (3), and a connector member (33), wherein the connector member (33) comprises a spring clip that includes flexible spaced prongs that resilient deform toward each other as the prongs are inserted in the cap member central opening to permit assembly of the cap and saddle members together. The prongs of the connector member (33) are spaced sidewalls having internal recesses therein, and the cap member includes radial flanges for being received in the recesses to keep the cap member axially fixed as the cap member is turned to the locked position thereof (FIG 4). It therefore would have been obvious to one skilled in the art to modify the spinal fixation system taught by Yuan et al. by having the connector member be a spring clip, like that taught by De Coninck et al., because the spring clip provides a stronger frictional force for maintaining the connection between the cap member and the saddle member.

9. Claims 13, 20, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yuan et al. (U.S. Patent 6,565,565) in view of Beaurain et al. (U.S. Publication 2005/0107788).

Yuan et al. disclose a spinal fixation system (FIG 12A) for fixing a spinal rod in a desired position relative to a patient's spine, the spinal fixation system comprising: a bone anchor member (224) for being secured to a vertebral bone of the spine. A head (225) at the proximal end of the anchor member having an upper recessed surface and a lower generally arcuate external surface (FIG 12A). Additionally, there is a coupling member (222) for receiving the spinal rod (212) and including an internal seat surface (229) and a

central bore sized to allow the anchor member to extend therethrough in a plurality of different orientations with the arcuate external surface of the head bearing on the internal seat surface of the coupling member to allow the anchor member head to shift thereon (FIG 13), and a clamping member (220) that clamps the rod against the coupling member (222) to fix the anchor member head against the seat surface with the anchor member in one of the different orientations thereof.

The clamping member (220) comprises a saddle member (220b) having an upper cam surface, and a cam lock member (220b) axially adjustably connected to the saddle member and having a lower cam surface that cooperates with the saddle upper cam surface so that turning of the cam lock member toward a locked position thereof drives the saddle member axially toward the rod with the cam lock member staying axially fixed (FIG 12B).

However, Yuan et al. fail to disclose a low profile insert that fits within a recess in the head of the bone anchor member. Beaurain et al. disclose a spinal fixation system comprising a bone anchor member (10) with a head (10) having a recess and a low profile insert (3) in the form of an anvil, placed within the recess (FIG 1). The low profile insert (3) has a substantially flat upper surface for engaging a spinal rod and a spherical, arcuate lower surface for adjustably bearing against the recessed surface of the anchor member head with the insert sized so that the upper surface thereof projects only slightly beyond the anchor member head to keep the profile of the insert to a minimum (FIG 1). The low profile insert (3) is shiftable within the recess to orient the top surface of the insert against an external surface of the spinal rod (FIG 1). It therefore would have been obvious to one

skilled in the art to modify the system taught by Yuan et al. by having the anchor member head comprise the recess and insert taught by Beaurain et al., because it provides a support wall for the spinal rod, while still allowing the rod to be placed in different orientations, depending on the patient (see Beaurain et al.; Paragraph [0007] - [0013]).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELANA B. FISHER whose telephone number is (571)270-3643. The examiner can normally be reached on Monday through Friday from 8:30AM to 5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571)272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elana B Fisher/
Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733